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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/430,050	10/29/1999	MICHAEL S.H. CHU	1001.1258101	6707

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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/430,050	CHU ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-9,11-15,21 and 24-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-9, 11-15, 21 and 24-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-9, 11-15, 21 and 24-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Heck, 6,083,207. Heck discloses means (212) for breaking said valve body along a predetermined location; means (70, 71) for coupling said valve body to a peel-away sheath for coupling said peel-away sheath lumen to said valve body lumen; means (50) for receiving a compressible valve sleeve having a lumen therethrough for coupling said valve sleeve lumen to said valve body lumen; and means (52 and 56) for compressing said valve sleeve for restricting any fluid flow from said peel-away sheath lumen through valve and valve sleeve lumen. A compressible valve sleeve is disclosed as a medical device, see column 5, lines 33-34, column 9, lines 18-19), wherein the proximal end of the valve sleeve extends proximal of said means for compressing said valve sleeve.

As to claim 2, the valve sleeve inherently includes a free end extending past said means for compressing, and further comprising means (206) for receiving a catheter tip

within said valve sleeve lumen free end while said means for compressing is compressing said valve sleeve, such that said valve sleeve lumen is substantially occluded by said inserted catheter tip while said catheter tip is inserted.

As to claim 3, Heck discloses a means (52, 20 and 56) for reversibly restricting fluid flow from said sheath lumen coupled to said sheath proximal end; means (70, 71) for breaking apart said fluid flow restricting means responsive to applied force; and means (50) for admitting a catheter distal end into said valve.

As to claim 4, the means (52, 20 and 56) for reversibly restricting flow has an open position for allowing flow therethrough and a closed position for substantially restricting flow, wherein said means (50) for admitting said catheter distal end includes means for admitting said catheter distal end while said means for restricting flow is in said closed position,.

As to claim 5, said means (52, 20 and 56) for restricting flow includes a flexible, constrictable tube (20) having a lumen therethrough.

As to claim 6, said means (52, 20 and 56) for restricting flow includes means (52) for pinching said flexible tube for constricting said flexible tube lumen.

As to claim 7, said means for pinching has at least two portions (26, 28) movable with respect to each other, said two portions having means (52) for accepting and pinching said flexible tube therebetween, said two portions together having an open position and a closed position.

As to claim 8, said movable pinching member portions are hingedly coupled together with at least one hinge, see column 7, lines 33-36, and see Figure 3.

As to claim 9, said sheath has a longitudinal axis and said at least one hinge has an axis substantially parallel with said sheath longitudinal axis and said hinge enables movement of said pinching member portions about said hinge longitudinal axis for pinching said flexible tube in said closed position, see column 7, lines 33-36, and see Figure 3.

As to claim 11, when in said closed position, said pinching members (52 and 56) include means for leaving sufficient space in said flexible tube lumen for passage of a guide wire.

As to claim 12, Heck discloses a tubular, distal introducer sheath (20) having a proximal region and a lumen therethrough, said sheath having at least one longitudinal strip (212) for preferentially tearing said sheath along said strip, see column 9, lines 7-9; a tubular, flexible, proximal valve sleeve (medical device, see column 5, lines 33-34, column 9, lines 18-19) having a proximal region, a distal region, and a lumen therethrough; and a valve body (12) having a lumen therethrough and being sealingly coupled to said introducer sheath proximal region, said valve having at least one weakened region (near 94) for preferentially splitting said valve into at least two pieces responsive to an applied breaking force, said valve body having a seat (50) for mating to said proximal valve sleeve distal region, said valve body including a pinch member (52) for pinching said flexible valve sleeve and having a closed position for constricting fluid flow through said valve sleeve and an open position for admitting a catheter inserted through said valve sleeve.

As to claim 13, said flexible valve sleeve includes a free portion proximal of said pinch member for admitting said catheter into said sleeve free portion while said pinch member is in said closed position.

As to claim 14, said valve body pinch member (52) includes a recess therein for allowing passage of a guide wire through said pinch member while said pinch member is in said closed position.

As to claim 15, Heck discloses a breakaway distal portion (20) having a lumen therethrough for receiving said introducer sheath proximal region; and a proximal portion (12) including two opposed valve body members (26, 28), at least one of which is movable relative to the other and having concave surfaces therebetween for receiving a flexible valve sleeve therebetween, said valve body opposed members having an open position and a closed position, wherein said valve body members move apart relative to each other to reach said open position and said valve body opposed members move together relative to each other to reach said closed position, see column 7, lines 33-37, and column 8, lines 26-30) wherein said flexible sleeve has a lumen therethrough and said sleeve and sleeve lumen are constricted between said body members in said closed position, such that fluid flow through said sleeve is substantially restricted in said closed position.

As to claim 21, said valve body members (26, 28) are considered pivotally mounted to each other along at least one hinge oriented substantially parallel to said valve body lumen longitudinal axis, see column 7, lines 33-37, and column 8, lines 26-30.

As to claims 24 and 28, a sheath receiver is disclosed at (16). Moreover, when the compressible valve sleeve is received by the pinch member and the introducer sheath, fluid communication is created from the introducer sheath lumen into the compressible valve sleeve lumen.

As to claims 25, 26, 29 and 30 when the valve sleeve with a guidewire is received by the pinch member and the pinch member is in the closed configuration, fluid flow through the compressible valve sleeve is substantially prevented.

As to claims 27 and 31, a valve sleeve seat (see distal end of 13) for receiving a distal end of a compressible valve sleeve, wherein the valve sleeve seat is located between the pinch member and the sheath receiver.

Response to Arguments

Applicants' arguments filed September 29 , 2003 have been fully considered but they are not persuasive.

Applicant argues that the standard definition of a hemostasis valve seals around a device, as opposed to being pinched off, see page 4 of Applicant's response. Examiner asserts that this argument is not persuasive because it is irrelevant since Applicant is referring to hemostasis valves other than the Heck hemostasis valve, which operates differently.

Applicant also argues on the top of page 5 that the catheter must be kept open for another device to pass through it. Examiner asserts that a catheter that is compressed between lips (56) in the Heck valve (see Figure 6) can still have devices

(such as a guidewire) pass through it while the lips (56) maintains pressure on the catheter (see column 6, lines 43-46.) Applicant also argues on the bottom of page 6 that the cites language in Heck does not suggest any indication of compression.

Examiner would like to point out that "compress" according to Webster's 10th edition, means to press or squeeze together, and "compressible" means capable of being compressed. Thus, the catheter is "compressible" in that it is capable of being compressed, and the means (52 and 56) for compressing the catheter compresses the catheter in that it presses or squeezes the catheter to limit blood flow during the introduction of a medical device through the sheath, see column 2, lines 33-36.

Applicant also points out on top of page 6 of Applicant's response that Heck cites references that suggest that it is undesirable to pinch a catheter inserted through a hemostasis valve.

In response, Examiner notes that Heck cites in the "Background" section patents that disclose hemostasis valves. Examiner asserts that the problems that these patents intended to overcome, i.e., undue pressue that narrows the catheter's diameter thereby altering measurement parameters within the catheter, does not mean that Heck's device does not pinch the catheter positioned within the device. Heck's purpose is to provide a valve that limits blood flow during introduction of a medical device such as a catheter, see column 2, lines 33-36, and the valve that Heck discloses must pinch the medical device in order to prevent blood flow.

Applicant also argues on pages 8-11 that the prior art cited in Heck does not seal by compressing a device. Examiner asserts that the prior art are irrelevant because the

Heck device is structurally different and thus operates differently from those prior art devices. In any case, Examiner reasserts that the catheter is "compressible" in that it is capable of being compressed, and the means (52 and 56) for compressing the catheter compresses the catheter in that it presses or squeezes the catheter to limit blood flow during the introduction of a medical device through the sheath, see column 2, lines 33-36.

Applicant also argues on page 12 that the compressible valve sleeve is distinct from a catheter, see page 12, lines 14-15. Examiner asserts that the catheter in Heck is a sleeve and it is capable of being compressed and it is capable of being part of a valve in that it limits blood flow, see column 2, lines 33-36. Thus, the catheter is considered a compressible valve sleeve. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Applicant also argues on page 14 that Heck does not disclose a valve seat for mating to said proximal valve sleeve distal region. Examiner reasserts that element (50) is a valve seat for mating to the catheter. Element (50) is a receiving area into which a medical device, such as a catheter, can be inserted, see column 6, lines 28-29.

Examiner would also like to emphasize that Applicant has not defined how the valve seat mates with the proximal valve sleeve distal region.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-TH 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

Mary E. Ceperley
MARY E. CEPERLEY
PRIMARY EXAMINER
AU 1644

A.L.
December 27, 2003